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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/766,253 01/19/2001 Thomas R. Cech 015389002921

22869 7590 08/26/2002

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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/26/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,253	CECH ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 August 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 8-14 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14 and 18-20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 8-12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Applicant's election without traverse of group I, claims 8-12 in Paper No. 12 is acknowledged.

2. The disclosure is objected to because of the following informalities:

In the section "Brief Description of the Drawings", the specification should be amended to refer to and describe each of the embodiments of the figures. See, for example, Figures 1A- B and 7A-B.

3. Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-12 are indefinite over the recitation of "corresponding" because this is not an art recognized term to describe the relationship between two nucleic acid sequences. It is not clear whether this refers to sequence homology/similarity or to sequence complementarity and it is not clear what percentage of homology or complementarity is encompassed by "corresponding" or under what types of conditions "corresponding" nucleotides are determined. Specifically, it is not clear as to whether the claims intend to recite that the sample is suspected of including a polynucleotide that is the complement of SEQ ID NO: 100 since the probe itself consists of the sequence of SEQ ID NO: 100 or a fragment thereof. In order for a hybridization complex to form, the probe and sample must contain nucleic acids which are complementary to one another rather than identical to one another.

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Claims 8-12 are indefinite over the recitation of “said nucleotide”. The claim previously refers to a “nucleotide sequence of SEQ ID NO: 100, or a fragment thereof”. Since a single “nucleotide” is not usually employed as a probe, the claims are confusing over the recitation of “said nucleotide”. This rejection may be overcome by amendment of the claims to recite “said nucleotide sequence”.

Claims 8-12 are indefinite because the claims do not recite a positive process step which agrees back with the preamble. The claims are drawn to a method for detecting the presence of a polynucleotide sequence encoding at least a portion of a human telomerase. However, the final process step is one of detecting a hybridization complex. The claims require the use of a probe consisting of SEQ ID NO: 100 or consisting of a fragment thereof. Because the probe may consist of any fragment of any length of SEQ ID NO: 100, the probe will hybridize to both nucleic acids which encode telomerase and nucleic acids which do not encode telomerase. Thereby, the presence of a hybridization complex between the probe and the sample nucleic acid does not necessarily indicate the presence of a polynucleotide encoding at least a portion of a human telomerase. Accordingly, it is unclear as to whether the claims are intended to be limited to methods which detect the presence of a polynucleotide encoding at least a portion of a human telomerase or whether the claims are intended to be limited to methods which detect the presence of a hybridization complex formed between the polynucleotide of SEQ ID NO: 100, or any fragment thereof, and a sample nucleic acid.

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4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over NCI-CGAP (GenBank Accession No. AA281296; April 2, 1997) in view of Schena (Proceedings of the National Academy of Sciences, USA (October 1996, Vol 93, pages 10614-10619).

NCI-CGAP (GenBank Accession No. AA281296; 4/2/97) discloses a cDNA clone isolated from a human cDNA library. The cDNA consists of a 389 bp fragment which is contained within instantly disclosed SEQ ID NO: 100. NCI-CGAP does not teach hybridization methods using the cDNA as a probe.

Schena teaches hybridization methods in which cDNAs from ESTs are attached to a solid support and used as a probe to detect cognate human genes (see abstract and page 10614-10615).

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Schena teaches that the hybridization method is useful for identifying new genes and characterizing and monitoring the expression of genes complementary to the cDNA probes.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the cDNA clone of NCI-CGAP as a probe in the hybridization method of Schena in order to have generated a hybridization method that would have allowed one to further characterize and monitor the expression of genes complementary to the cDNA clone of GenBank Accesssion No. AA281296 and/or would have allowed one to have detected and isolated the gene for the cDNA or genes sharing sequence identity with the cDNA. It is noted that the resulting method would necessarily detect the presence of a polynucleotide comprising the sequence of instant SEQ ID NO: 100, if said polynucleotide was present in a sample, since the probe of NCI-CGAP is fully complementary to the complement of SEQ ID NO: 100. With respect to claim 12, given the hybridization conditions disclosed by Schena, the resulting method would have allowed for the detection of polynucleotides which differ from SEQ ID NO: 100 in that they contain sequence alterations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

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Carla Myers

August 22, 2002

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER